Application No. 10/596,876
AMENDMENT dated January 1, 2011

Amendments to the Claims

The following Listing of Claims replaces all prior versions and listings of claims in the application.

Listing of Claims

1-44. (cancelled)

- 45. (previously presented) A pharmaceutical composition comprising a mixture that is not a molecular dispersion of the following components:
 - (1) at least 50 wt% of particles, said particles comprising a low-solubility drug and a poloxamer, wherein at least 75 wt% of said drug is amorphous; and
 - (2) a concentration-enhancing polymer.
- 46. (previously presented) The composition of claim 45 wherein said concentration-enhancing polymer is selected from the group consisting of hydroxypropyl methyl cellulose acetate succinate, hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, carboxymethyl ethylcellulose, and mixtures thereof.

47-48. (cancelled)

- 49. (withdrawn) A process for preparing a solid composition comprising the steps
 - (1) forming a solution consisting essentially of a low-solubility drug, a poloxamer, and a solvent; and
 - (2) removing said solvent from said solution to form said solid composition consisting essentially of said low-solubility drug and said poloxamer, at least a substantial portion of said drug in said composition being amorphous;

Wherein said drug has a glass transition temperature of at least 50°C.

50. (withdrawn) A process for preparing a solid composition comprising the steps

- (1) forming a solution consisting essentially of a low-solubility drug, a poloxamer, and a solvent; and
- (2) removing said solvent from said solution to form said solid composition consisting essentially of said low-solubility drug and said poloxamer, at least a substantial portion of said drug in said composition being amorphous;

 Wherein said drug has a Log P value greater than about 6.5.
- 51. (withdrawn) The process of claims 49 or 50 wherein step (2) is selected from the group consisting of spray drying, spray coating, rotoevaporation, and evaporation.
- 52. (withdrawn) The products of the process of claims 49 or 50.
- 53. (previously presented) The composition of claim 45 wherein component (1) is a solid solution of said drug homogeneously distributed throughout said poloxamer.
- 54. (previously presented) The composition of claim 45 or 53 wherein said mixture is a dry physical mixture.
- 55. (currently amended) The composition of claim 45 or 53 wherein components (1) and (2) of said mixture is are present in different regions of said composition
- 56. (currently amended) The composition of claim 55 wherein <u>components (1) and (2)</u> of said mixture is are present in different layers of a multi-layer tablet.
- 57. (new) The composition of claim 55 wherein said mixture is present in the same environment of use after components (1) and (2) have been co-administered to said environment of use at a time ranging from approximately the same time to within 60 minutes of each other.
- 58. (previously presented) The composition of claim 45 or 53 wherein said drug has a glass-transition temperature of at least 50°C.

- 59. (previously presented) The composition of claim 45 or 53 wherein said drug has a Log P value of greater than 6.5.
- 60. (previously presented) The composition of claim 45 or 53 wherein said drug has a melting point of T_m in K, and wherein said drug has a glass-transition temperature of $T_{g,drug}$ in K, and wherein the ratio of said melting point to said glass transition temperature, $T_m/T_{g,drug}$, is less than 1.4.
- 61. (previously presented) The composition of claim 45 or 53 wherein said ratio of said melting point to said glass-transition temperature, $T_m/T_{g,drug}$, is less than 1.35.
- 62. (previously presented) The composition of claim 45 or 53 wherein said ratio of said melting point to said glass-transition temperature, $T_m/T_{g,drug}$, is less than 1.3.